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Title: Vulval malignancies - A two decade analysis from Eastern India

Introduction

•Rare disease - 1.3% of all gynaecological malignancies.
•Predominantly disease of elderly women, now becoming common in younger age.
•Paucity of literature from developing countries.
•FIGO 2009/2021 staging - positive PLNs staged as IVB, along with patients that have distant metastases.
•Now a days with newer techniques RT they seem to have better prognosis similar to positive inguinal nodes.

AIM & Objectives

•To study the **clinico-pathological & clinico-surgical** characteristics and **survival outcomes** of vulval cancer in our patient population.
•Primary objective -To study clinicopathological characteristics, demographic pattern of invasive vulvar cancer, analyse surgical options, postoperative complications, failure pattern, and survival outcomes in our institute.
•Secondary objective - To evaluate the outcome of positive pelvic lymph nodes on prognosis and survival.

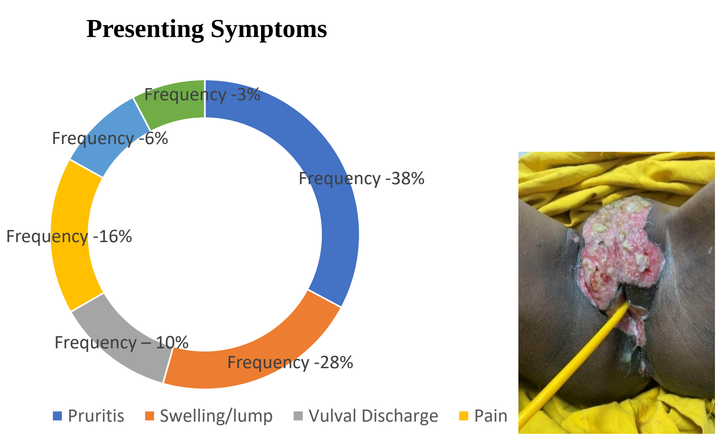
Materials and Methods

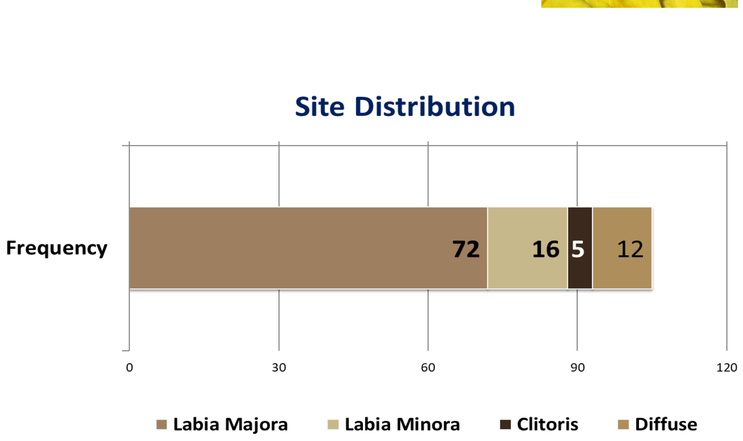
•Retrospective study
•Time period- **2001 - 2024**
•**Inclusion criteria** - Patients with **biopsy proven invasive vulvar cancer**
•Institute - AHPGIC, Cuttack
•Surgical management - RV, MRV/WRLE and =/- unilateral/bilateral IFND - lazy S incision below inguinal ligament and RT/NACT/NART/CRT.
•**FIGO 2009 (later pts re-categorised into FIGO Staging 2021) / AJCC Staging followed.**
•PLNs positive if they contained **biopsy-proven disease, FDG PET/CT positive or were 1.5 cm or larger in SAD on CT or MRI.**
•Adjuvant EBRT/CCRT was given with **50 Gy in 2 Gy per fraction with cisplatin, once daily 5 days a week**, for 5 weeks, if indicated.
•Follow up **three monthly for 2 year, six monthly for 3 years and yearly thereafter.**
•Survival analysis was done using **Kaplan-Meier method** with **SPSS 17** (SPSS Inc, USA) for Windows Software.

Result

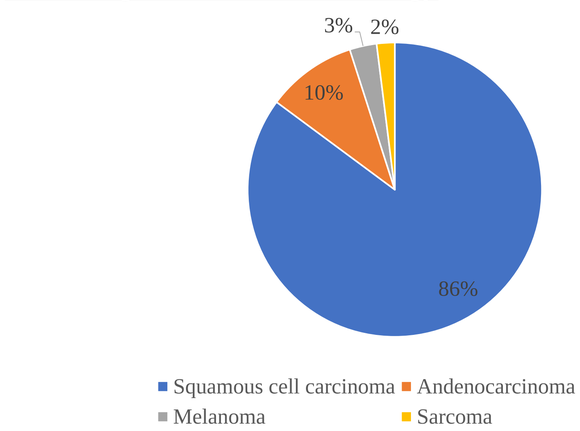
Characteristics	Value
Mean Age	55.6 years
Parity	Nulliparous-16.2% Multiparous-83.8%
Comorbidities	Present-37.3% Absent:-45.2%, Not known-7.5%
Stage	Stage-1:-**22**, Stage:-2:**60**, Stage-3:-**8,** Stage-4:-**15**
Mean Tumour Size	3.9cm
Grade(SCC & AC)	WD-61, MD-21, PD-8

Demographic characteristic of Patient population





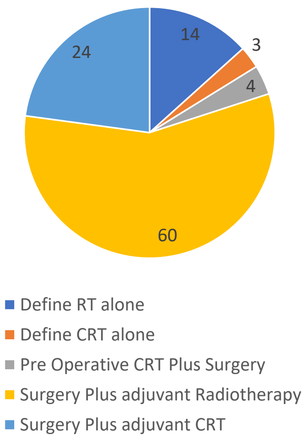
Percentage distribution Histology



Management of Vulva and Groin

Treatment of Vulva**:-(N:-105)**
Definite RT alone**:-14**
Definite CRT alone**:-3**
Preoperative CRT plus Surgery**:-4**
Surgery plus adjuvant Radiotherapy**:-60**
Surgery plus Adjuvant CRT**:-24**
Total Surgery=88

Treatment of Groin/Pelvis:- (N-82)
CRT alone-7
RT alone-8
LND+RT:-55
LND+CRT:-12



Surgical Procedure

Surgery for Primary Tumour	Number of Patients	Node Dissections
Radical Vulvectomy	**48**	**U/L-8** **B/L-35** **None-5**
Modified radical Vulvectomy/WRE	**40**	**Unilateral-14** **Bilateral-10** **None:-16**

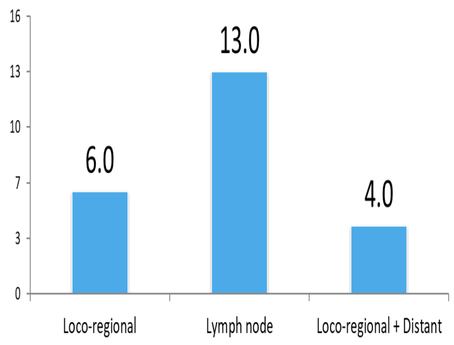
Flap reconstruction done in 31/88 pts (35.22%) , most common being the lotus petal flap.

Lymph node and Margin status in upfront surgically treated patients

- The **average number of nodes retrieved was 8.**
- **38 of 105 patients did not have any lymph node involvement** hence nodal dissection was not done.
- **Margin was positive only in 6.1 % cases**, in these cases 2/6 had local recurrence and 1/6 had distant recurrence.
- Routine SLNB is yet to be practiced at our institute. We routinely practice saphenous vein sparing.

Follow up and Recurrence

❑ Median follow-up - **87 months**
❑ **21 patients** were lost to follow-up



- Recurrence in 23 pts (23/84-27.38%).
- Median time to relapse was 18 months.
- All pts with groin recurrence died.
- No case of isolated distant metastases was seen

Post Operative Complications

Complications	Frequency	Percentage(%)
Lymphocyst	30/67	44.77
Flap Necrosis	7/31	22.58
Wound Infection	31/88	35.22
Deep Vein Thrombosis	2/88	2.27
Lower leg Lymphedema	19/67	28.35

- **MC complication was lymphocyst formation** which was treated with repeated aspirations.
- The incidence of lower leg lymphedema was 28.35% which **points to the need of employing SLN procedure in practice.**

Overall DFS and OS

- **The estimated overall 5-year DFS and OS in our series were 71.4% and 87.1%, respectively.**
- **The OS for LN (Inguinal/Pelvic) negative versus LN positive pts was 56.2 months vs 31.1 months. (p value <0.001).**
- **Stage & lymph node positivity significantly affected OS on univariate analysis also in other Indian series.**
- **The 5 yr OS of vulval melanoma (35.6%) and vulval sarcoma (45.3%) was significantly worse compared to SCC(89.4%) and AC(70.3%).**

Pelvic Lymph Node

- **11 Pts with IFLN Positive had PLN positive** also (All > stage I pts - **Biopsy proven in 6 cases only**).
- All patients had squamous cell carcinoma (SCC).
- Whether or not surgical resection of positive PLNs would be of benefit is difficult to know.
- Microscopic PLN involvement is therefore rarely diagnosed.
- Clinically negative PLNs are rarely dissected **(Post GOG 37**) and irradiated prophylactically at the same time as inguinal RT is delivered.

Pelvic Lymph Node(N-11)	Value
CT/MRI	8
PET CT	3
Mean Size(cm)	3.1
Medial/Lateral lesion	7/4
RT/CRT	6/5
5 year DFS/OS	**51.7/57.3**
Recurrence	4 (3 Groin, 1 distant including pelvic LN)

DFS & OS:- 51.7/57.3

- Our data demonstrate that **locoregional treatment with definitive or adjuvant RT can be curative for many patients with PLN-positive** stage IVB vulvar cancer.
- The OS and DFS for these patients was same as patients with M0 disease with positive inguinal nodes **(i.e., FIGO stage III disease- DFS -57.8% and OS 61.2%).**
- The **OS & DFS was highly significant between the PLN group and stage IVB- DFS -32.6% and OS -40.1% (p<0.001).**
- ***For this reason, we strongly recommend modification of the FIGO IVB classification to more realistically reflect the relatively favorable prognosis of patients with PLN involvement & include with stage IIIB/C.***

Discussion

- **PET/CT - 95% specificity in detecting PLN/PALN metastases in patients with pelvic malignancies.**
- Our study demonstrates that several decades of advances in multimodality treatment have not only led to better results for patients with inguinal nodal metastases but **also made it possible to cure many patients with PLN involvement.**
- In this context, it **seems inappropriate to group patients who have PLN involvement with patients who have distant metastases, which are nearly always incurable**.

Pros and Cons of the study

Pros	Cons
Effectively a large study over a period of 20 years.	Long time period resulted in change in management techniques (newer RT techniques).
Biggest tertiary referral centre of Odisha.	Retrospective analysis in one centre.
Uniform management practices.	All pts did not have biopsy proven PLN.
All histologies were included.	Not all pts underwent metastatic work-up especially early-stage pts.

Conclusion

❖ Stage and nodal positivity were significant prognostic factors for survival on univariate analysis in our series.

❖ Aggressive locoregional treatment can lead to favorable outcomes for many patients with grossly involved PLNs that is comparable to that of grossly involved inguinal nodes only.

❖ ***We recommend modification of the FIGO stage IVB classification to more accurately reflect the relatively favorable prognosis of patients with PLN involvement.***

References

1.de Martel C, Ferlay J, Franceschi S, et al. Global burden of cancers attributable to infections in 2008: a review and synthetic analysis. Lancet Oncol. 2012;13:607-615.
2. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A.Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68:394-424.